

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Norfolk Division

CAREFIRST OF MARYLAND, *et al.*,

Plaintiffs,

v.

JOHNSON & JOHNSON, *et al.*,

Defendants.

Case No. 2:23-cv-629

**OPINION & ORDER**

Plaintiffs CareFirst of Maryland, Inc., Group Hospitalization and Medical Services, Inc., and CareFirst Bluechoice, Inc. (collectively “CareFirst”) move for partial summary judgment, and Defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively “J&J”) move for summary judgment. ECF Nos. 441, 442. CareFirst also moves to exclude the expert opinions and testimony of Anupam Jena (ECF No. 450), which J&J relies on in support of its monopoly power arguments, and J&J moves to partially exclude the expert opinions and testimony of Nicole Maestas (ECF No. 435), CareFirst’s rebuttal expert on monopoly power.

For the reasons stated herein, the motions to exclude will be **DENIED**, CareFirst’s motion for partial summary judgment will be **DENIED**, and J&J’s motion for summary judgment will be **GRANTED IN PART** and **DENIED IN PART**.

## I. BACKGROUND

The following undisputed facts are sufficient to enable the Court to decide the parties' summary judgment motions:

1. J&J's Stelara (Ustekinumab) is a monoclonal antibody that the U.S. Food & Drug Administration (FDA) has approved for treatment of psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis (UC). ECF No. 492 at 9 ¶¶ 1–2; ECF No. 566 at 8.

2. J&J has manufactured and sold Stelara in the U.S. since 2009. ECF No. 474 at 13 ¶ 1; *see* ECF No. 576 at 41.

3. From its launch and through December 31, 2024, J&J was the sole U.S. supplier of Ustekinumab. ECF No. 474 at 13 ¶ 2; *see* ECF No. 576 at 41.

4. J&J had initial patent coverage for Ustekinumab under U.S. Patent No. 6,902,734 (the '734 patent) at least through September 25, 2023. ECF No. 474 at 13 ¶ 3; *see* ECF No. 576 at 41 ¶ 1 (asserting that patent coverage extended longer but not disputing this fact).

5. In or before December 2014, J&J began seeking FDA approval to use Stelara to treat moderately to severely active UC. ECF No 474 at 36 ¶ 47; *see* ECF No. 576 at 46. J&J sought approval to go directly to Phase 3 trials, given certain genetic similarities between UC and Crohn's disease and because J&J had clinically proven Stelara is a safe and effective treatment for Crohn's disease. ECF No. 492 at 11 ¶ 8; *see* ECF No. 566 at 9 ¶ 8.

6. To support FDA approval, in July 2015, J&J developed a direct-to-Phase 3 clinical trial (NCT 236) titled “A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants with Moderately to Severely Active Ulcerative Colitis (UNIFI).” ECF No. 492 at 10 ¶ 5; ECF No. 474 at 36–37 ¶ 47; *see* ECF No. 576 at 45–46.

7. J&J publicly posted information about NCT 236 to the FDA’s website for clinical trials, ClinicalTrials.gov (CT.gov), and kept the CT.gov posting updated to reflect changes to the study protocol or its status. ECF No. 474 at 37 ¶¶ 48–49; *see* ECF No. 576 at 45–46. Each update created a new version of the record that was preserved in the history tab of the NCT 236 homepage on CT.gov. ECF No. 474 at 37 ¶ 49; *see* ECF No. 576 at 45–46.

8. The CT.gov postings specified the primary and secondary outcome measures used to assess the results of the study. ECF No. 474 at 38 ¶ 54; *see* ECF No. 576 at 45–46.

9. On September 24, 2018, J&J submitted to the U.S. Patent and Trade Office (PTO) provisional patent application 62,735,501 (the ’501 application), which claimed methods of treating moderately to severely active UC by administering Stelara. The ’501 application served as a basis for the non-provision application 16/580,509 (the ’509 application), filed on September 24, 2019, by J&J Assistant General Counsel Eric Dichter. ECF No. 492 at 13 ¶ 15; ECF No. 474 at 38 ¶¶ 56–57; *see* ECF No. 576 at 45–46.

10. The '509 application stated that “biologic therapies that are currently approved for the treatment of UC have also demonstrated efficacy in Crohn’s disease.” ECF No. 492 ¶ 17; *see* ECF No. 566 at 10 ¶ 17. The application also discusses that UC and Crohn’s disease are “mediated by Th1 or TH17 cells” and the genetic relationship between the two and states that the “efficacy and safety of intravenous (IV) [U]stekinumab as induction therapy in Crohn’s disease have been evaluated in clinical studies” where “[U]stekinumab demonstrated clinically significant efficacy compared with placebo.” ECF No. 566 at 10 ¶ 17.

11. The patent examiner issued an initial non-final rejection of the '509 application on the grounds that the CT.gov August 13, 2018 posting rendered the application obvious and anticipated. ECF No. 576 at 46 ¶ 15; ECF No. 492 at 15 ¶ 20; *see* ECF No. 566 at 10.

12. In response to the non-final rejection, Dichter amended the claims to include the UNIFI’s study’s specific clinical endpoints. ECF No. 492 at 15 ¶ 21; *see* ECF No. 566 at 10.

13. The patent examiner issued the patent on March 30, 2021, as U.S. Patent No. 10,961,307 (the '307 patent), set to expire in September 2039. ECF No. 492 at 15–16 ¶ 23; *see* ECF No. 566 at 10. The '307 patent is a method-of-use patent. ECF No. 474 at 39 ¶ 58; *see* ECF No. 576 at 46.

14. The patent examiner listed the full CT.gov website on a Notices of References cited, with the annotation “[a]ccessed from the internet 7/13/2020.” ECF No. 492 at 18 ¶¶ 28; *see* ECF No. 566 at 10 ¶ 28.

15. In 2019, J&J began exploring opportunities to acquire a neonatal Fc receptor-inhibitor drug, including Momenta's nivalimab. ECF No. 492 at 18–19 ¶¶ 30–31; *see* ECF No. 566 at 10. The appropriation request asking J&J's board of directors to approve the Momenta acquisition attributed 95% of the deal's value to Momenta's nivalimab product. ECF No. 492 at 19 ¶ 32; *see* ECF No. 566 at 10.

16. At the time of the acquisition, Momenta's patent portfolio consisted of over 500 patents, including the following four patents: U.S. Patent Nos. 8,852,889 (expiring July 6, 2032), 9,217,168 (expiring March 14, 2033), 9,475,858 (expiring July 6, 2032), and 9,663,810 (expiring March 14, 2033) (the "Momenta manufacturing patents"). ECF No. 474 at 21 ¶ 16; ECF No. 492 at 19 ¶ 34; *see* ECF No. 576 at 44 ¶ 9; ECF No. 566 at 11; *see* ECF Nos. 456-15, 456-16, 458-1, 458-2 (patents). These patents related to cell culture media used in the manufacturing process of biologic drugs. ECF No. 492 at 19 ¶ 34; *see* ECF No. 566 at 10 ¶ 28. Their intended use was to create biosimilar copies of biologic drugs. ECF No. 474 at 23 ¶ 28; *see* ECF No. 576 at 45.

17. In August 2020, J&J's acquisition counsel reviewed a draft version and ultimately signed a merger agreement that listed the patents J&J would acquire from Momenta, including all four Momenta manufacturing patents. ECF No. 474 at 22 ¶¶ 18–19; *see* ECF No. 576 at 44.

18. Around the same time, J&J began "litigation diligence" regarding biosimilar competition for Stelara. ECF No. 474 at 22 ¶ 22; *see* ECF No. 576 at 45.

19. J&J's merger with Momenta closed on October 1, 2020, and J&J acquired exclusive control over all Momenta patents. ECF No. 474 at 23 ¶ 23; *see* ECF No. 576 at 45.

20. J&J has not divested, sold, or surrendered its interests in the Momenta manufacturing patents. ECF No. 474 at 23 ¶ 25; *see* ECF No. 576 at 45.

21. In November 2022, Amgen informed J&J that it intended to launch its Ustekinumab biosimilar upon FDA approval in or around May 2023. ECF No. 474 at 25 ¶ 36; *see* ECF No. 576 at 45. On November 29, 2022, J&J sued Amgen for infringement of its Ustekinumab composition patent (the '734 patent) and its method-of-use patent for the use of Ustekinumab to treat UC (the '307 patent). ECF No. 474 at 26 ¶ 37; *see* ECF No. 576 at 45.

22. On February 21, 2023, J&J amended its complaint against Amgen to allege infringement of the Momenta manufacturing patents. ECF No. 474 at 26 ¶ 40; *see* ECF No. 576 at 45.

23. On May 19, 2023, J&J settled its claims against Amgen, granting Amgen a license to use the Momenta manufacturing patents and the '307 patent as of January 1, 2025. ECF No. 474 at 26–27 ¶ 42; *see* ECF No. 576 at 45.

24. On October 31, 2023, the FDA approved the first biosimilar Ustekinumab, Amgen's Wezlana. However, Amgen did not sell Wezlana in the U.S. until January 2025. ECF No. 474 at 13 ¶ 4; *see* ECF No. 576 at 41–42.

25. In 2023 and 2024, J&J settled with six other Ustekinumab biosimilar manufacturers, granting licenses to use the Momenta manufacturing patents and the

'307 patent beginning in the first half of 2025. ECF No. 474 at 27–28 ¶¶ 43–44; *see* ECF No. 576 at 45.

## II. LEGAL STANDARDS

### A. Motions to Exclude Expert Opinions Under Fed. R. Evid. 702

Fed. R. Evid. 702 allows a “witness who is qualified as an expert by knowledge, skill, experience, training, or education” to “testify in the form of an opinion or otherwise” if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert’s opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702.

The proponent of the testimony “must establish its admissibility by a preponderance of proof.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). In assessing the admissibility of expert testimony, the district court must assess whether the testimony is both relevant and reliable. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993).

Expert testimony is relevant if it has “a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (quoting *Daubert*, 509 U.S. at 592). The test of reliability is “a flexible one” and considers whether the testimony “is supported by adequate

validation to render it trustworthy.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260–61 (4th Cir. 1999) (quoting *Daubert*, 509 U.S. at 594). The court focuses on the “principles and methodology employed by the expert, not the conclusions reached.” *Id.* (quoting *Daubert*, 509 U.S. at 595). Several factors may guide a judge’s determination of reliability, including whether the theory (1) can be or has been tested; (2) has been peer reviewed or published; (3) has a high known or potential error rate; and (4) enjoys general acceptance within the relevant scientific community. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

## **B. Summary Judgment**

A court may “grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). A “dispute about a material fact is ‘genuine’ . . . if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson*, 477 U.S. at 248.

“The party moving for summary judgment bears the initial burden of demonstrating the absence of a genuine dispute of material fact.” *Med. Mut. Ins. Co. of N. Carolina v. Gnik*, 93 F.4th 192, 200 (4th Cir. 2024); see *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). To do that, the movant must support their assertions as to undisputed facts by “citing to particular parts of materials in the record” or “showing that the materials cited do not establish the . . . presence of a genuine dispute, or that

an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1).

If the moving party is successful in the first instance, then the burden “shifts to the non-movant to ‘set forth specific facts showing that there is a genuine issue for trial.” *Gnik*, 93 F.4th at 200 (quoting Fed. R. Civ. P. 56(e)). “The facts and all justifiable inferences arising therefrom must be viewed in the light most favorable to the non-movant.” *Gnik*, 93 F.4th at 200 (citation omitted). However, if the non-movant “fails to properly support an assertion of fact or fails to properly address another party’s assertion of fact as required by Rule 56(c), the court may . . . consider the fact undisputed for purposes of the motion” or may “grant summary judgment if the motion and supporting materials . . . show that the movant is entitled to it.” Fed. R. Civ. P. 56(e).

### III. ANALYSIS<sup>1</sup>

The parties’ cross-motions for summary judgment seek relief on four elements: (1) CareFirst’s motion as to monopoly power; (2) J&J’s motion as to whether J&J committed fraud on the PTO; (3) the parties’ cross-motions as to whether J&J’s acquisition of Momenta manufacturing patents was anti-competitive; and (4) J&J’s motion as to antitrust injury.<sup>2</sup>

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<sup>1</sup> Throughout this Opinion and Order, where the Court relies solely on other district courts for a legal principle, the Court adopts that reasoning as persuasive based on its independent analysis of the principle at issue.

<sup>2</sup> CareFirst initially moved for summary judgment as to sham litigation regarding the ’307 patent. ECF No. 442. After the Court denied CareFirst’s motion for leave to file its third amended complaint as to sham litigation, ECF No. 592, CareFirst

### A. Monopoly Power

CareFirst seeks summary judgment on monopoly power. “Monopoly power is the power to control prices or exclude competition.” *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). A firm that “can profitably raise prices substantially above the competitive level” is a monopolist. *Dickson v. Microsoft Corp.*, 309 F.3d 193, 199 n.1 (4th Cir. 2002) (citation omitted). “A plaintiff can show that a defendant had monopoly power in a relevant antitrust market either directly or indirectly.” *United States v. Google LLC*, 778 F. Supp. 3d 797, 849 (E.D. Va. 2025) (citations omitted). Direct proof includes “evidence that a defendant profitably charged supracompetitive prices” while indirect proof “is derived from the structure and composition of the relevant market.” *Id.* (citations and quotation marks omitted).

Indirect proof also includes market share. *United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966) (“The existence of such power ordinarily may be inferred from the predominant share of the market.”). “[T]here is no fixed percentage market share that conclusively resolves whether monopoly power exists,” but courts have generally found monopoly power to exist where defendants control at least 70% of the market. *Kolon Indus. Inc. v. E.I. DuPont de Nemours & Co.*, 748 F.3d 160, 174 (4th Cir. 2014). Beyond market share, courts also look to other factors, such as “high barriers to entry, ability to price discriminate, [and] high profit margins,” which might demonstrate monopoly power. *Id.*; see *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S.

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withdrew its request for summary judgment as to sham litigation in its reply brief. ECF No. 629 at 22.

451, 481 (1992) (“Monopoly power under § 2 [of the Sherman Act] requires, of course, something greater than market power under § 1.”).

A monopoly power determination must begin with “a preliminary inquiry into market definition, which serves as a tool to determine the defendant’s market power.” *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 441 (4th Cir. 2011). A relevant antitrust market is generally defined as “the smallest group of sales for which the cross-elasticity of both demand and supply are sufficiently low that if a firm were the only seller in that group, it could . . . raise its price substantially above its marginal cost.” Hovenkamp, *IP & Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property* § 10.02(A) (2025). In short, a relevant market is one “within which significant substitution in consumption or production occurs.” *Ohio v. Am. Express Co.*, 585 U.S. 529, 543 (2018). To test whether products should be considered part of the same antitrust market, courts look to the cross-elasticity of demand between products, a key element of which is “the responsiveness of the sales of one product to price changes of the other.” *E.I. du Pont de Nemours & Co.*, 351 U.S. at 400.

Market definition consists of the relevant product market and the relevant geographic market. *E.I. du Pont de Nemours & Co.*, 637 F.3d at 441. Here, the parties do not dispute that the relevant geographic market is the United States and its territories. ECF No. 474 at 11. However, the parties contest the relevant product market. In support of their respective monopoly power arguments, CareFirst relies on the expert opinions of Nicole Maestas, which J&J moved to exclude in part (ECF

No. 435), and J&J relies on the expert opinions of Anupam Jena, which CareFirst moved to exclude (ECF No. 450). Therefore, the Court will first assess the admissibility of Maestas's and Jena's opinions.

*i. Nicole Maestas*

J&J seeks to exclude only one of Maestas's opinions—that “there is no evidence of economic substitution between Stelara and other products in the same therapeutic area.” ECF No. 436 at 6 (quotation marks omitted); ECF No. 488 ¶ 123. This opinion is admissible.

Maestas runs empirical regressions to analyze whether there is cross-elasticity of demand between Stelara and any other drugs. *See* ECF No. 488 ¶ 11. She explains that such an analysis requires a change in price, which can be best assessed by utilizing “price shocks that are caused by exogenous events (events outside of the control of the manufacturers of the focal products).” ECF No. 567 at 8 (emphasis removed); *see* ECF No. 470-6 ¶ 79. An “exogenous drop in price occurs when a new drug, whether brand or biosimilar/generic, enters the market.” ECF No. 567 at 9; *see* ECF No. 470-6 ¶ 82.

Maestas conducts two sets of “natural experiments” utilizing biosimilar launches and brand product launches.<sup>3</sup> ECF No. 488 ¶ 118. First, for potential

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<sup>3</sup> Maestas explains that the best way to estimate cross-price elasticity of Stelara would be to analyze data based on Stelara's biosimilar entry. ECF No. 488 ¶ 117. At the time of her report, sufficient data did not exist to do so. ECF No. 470-6 ¶ 79.

therapeutic substitute<sup>4</sup> drugs that experienced biosimilar entry during the time period—Humira and Remicade—her models show that “[i]f a drug is an economic competitor to Stelara, then Stelara’s price drop at its biosimilar entry would result in statistically significant changes in quantity demanded of the other drug.” ECF No. 470-6 ¶ 79. And “[i]f Stelara’s price change resulted in changes in quantity demanded for another drug, that implies that the reverse would be true,” which is “referred to as symmetry of cross price-elasticities.” *Id.* ¶ 80.

Second, “for drugs that did not experience biosimilar entries during the relevant time period,” she relies on “brand product launches as an alternative to determine whether the launch impacted Stelara’s quantity demanded. ECF No. 470-6 ¶ 81.

“A somewhat unique body of law has developed governing whether and under what circumstances statistical analysis proffered by an expert . . . pass muster under [Fed. R. Evid.] 702.” *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d 966, 973 (C.D. Cal. 2012). A regression analysis that “accounts for the major factors” will be admissible. *Bazemore v. Friday*, 478 U.S. 385, 400, 400 n.10 (1986) (Brennan, J., concurring in part) (“There may, of course, be some regressions so incomplete as to be inadmissible as irrelevant.”). In determining whether major factors have been

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<sup>4</sup> Drugs that are therapeutic substitutes treat the same conditions but are not necessarily economic substitutes. ECF No. 488 ¶ 106; *see* ECF No. 488 ¶ 107, n.332.

omitted, “[t]here must be some indication that the excluded variables would have impacted the results.” *In re Live Concert*, 863 F. Supp. 2d at 974.

J&J argues that Maestas’s regression analyses are unreliable because they do not account for “major factors” that affect Stelara demand. ECF No. 436 at 11. Specifically, J&J argues that Maestas does not: (1) control for Stelara’s approval for other indications, which would lead to an increase in quantity sold independent of new drug entry, or that other drugs may not have been approved for all indications; (2) account for the “massive increase” in the number of patients prescribed biologic drugs like Stelara or one of its potential clinical substitutes over time as doctors switched their patients from small molecule drugs to biologic drugs; and (3) account for changes in prevalence or diagnoses of the relevant conditions over time. ECF No. 436 at 14, 16. Therefore, if any of these factors constitute a “major factor” such that it would have “impacted the results” and rendered the regression “incomplete,” Maestas’s opinion would be inadmissible. The parties agree that the best way to determine if any of these factors are major is to test them. ECF No. 600 at 13; ECF No. 567 at 16.

Jena attempts to “correct” Maestas’s natural experiments by addressing each of these alleged failings (plus additional corrections) in one model. ECF No. 470-4 ¶¶ 199–201. To begin with, it is impossible to assess the importance of each individual factor from a new model that lumps together all purported missing factors. But in

any event, Maestas adequately explains why each factor is either accounted for or not necessary to the model.

First, Jena contends that Maestas errs by failing to “identify appropriate economic substitutes for patients with each” relevant condition and instead only estimating the “impact of a potential economic substitute’s entry on *total* retail prescriptions” for all conditions. ECF No. 470-4 ¶ 193. Jena concludes that composition of the group of patients treated with Stelara “changed significantly over time” and that J&J faced different competitors for patients with different conditions at different times. *Id.* But Maestas persuasively explains that market power should not be assessed at the indication level because what “matters from the seller’s point of view is how many *total* units they sell and at what price, not by any categorization of uses.” ECF No. 470-6 ¶ 75 (emphasis in original). Therefore, J&J does not “separate Stelara’s net sales or gross profits at the indication level” but rather focuses on total sales. *Id.* ¶ 76.

Additionally, Jena does not show that any indication approval date corresponded to a change of price, so it is unclear why controlling for indication approval dates would assist with an analysis of cross-elasticity of demand. ECF No. 470-6 ¶ 78. Maestas explains that a change in indication does not even provide the opportunity to model an “implicit change” in price like a product launch would. *Id.* ¶ 82. Therefore, Maestas sufficiently explains why she does not include an indication-

level factor in her analysis, and J&J does not demonstrate that the factor is necessary to the model or impacts the model in a way that makes Maestas's method unreliable.

Second, Jena asserts that Maestas fails to account for “the massive increase in patient demand for treatments” for each relevant condition. ECF No. 470-4 ¶ 196. Jena demonstrates that the number of patients prescribed Stelara “or one of its clinical substitutes” increased by 262% between 2011 and 2023. *Id.* Third, Jena argues that Maestas fails to account for “potential changes in the prevalence, diagnosis, and treatment” of the relevant conditions over time. ECF No. 470-4 ¶ 199. But Maestas asserts that she already includes a control variable that appropriately accounts for “changes in patient demand over time” and shows why her linear time trends (included in her regressions) sufficiently account for these factors. ECF No. 470-6 ¶¶ 103–109. Thus, Jena's concern is with whether Maestas accounted for these factors in the way that he proposes, not with whether she accounted for them in a way that is reliable. That, of course, is not a reason to exclude an expert opinion.

J&J also challenges Maestas's brand drug regressions because they are not based on price change. ECF No. 600 at 7–9. Maestas is clear that her brand drug regression is based on the “impact of the [brand product's launch] on Stelara's quantity demanded.” ECF No. 488 ¶ 119. Thus, she explains that “given that there is no price change at the time of a product launch, changes in quantity demanded at the time of a product launch are mainly useful for determining whether drugs are clinical substitutes.” ECF No. 470-6 ¶ 81. Where, as she concludes is the case here, there is

“no substitution at the time of a product launch,” that “implies there is neither clinical nor economic substitution.” *Id.*

The parties dispute the meaning and significance of Maestas’s deposition testimony that “there has to be a price change” in any regression analysis. ECF No. 600 at 7 (quoting ECF No. 542-5 at 4:14–17, 4:22–5:3). But her testimony is consistent with what she stated in her report: price change “really only makes sense for the biosimilar entries.” ECF No. 542-5 at 4:16–20. Therefore, while Maestas’s brand drug regression may not be a showing of cross-elasticity of demand, at the very least it is an admissible showing of clinical substitution, which J&J itself acknowledges is relevant in its opposition to exclude Jena’s opinions. ECF No. 572 at 25.

Finally, J&J challenges Maestas’s Humira biosimilar regression model because it “does not explain any variation in the quantity of Stelara demanded.” ECF No. 436 at 12 (emphasis removed). J&J argues that because “none of the coefficients on Maestas’s explanatory variables are statistically significantly different from zero,” the model is meaningless. *Id.* at 20 (emphasis removed). CareFirst, on the other hand, explains the “lack of statistical significance for the non-constant variables in the Humira model” are due to “no significant change in the outcome variable.” ECF No. 567 at 23–24 (emphasis removed). That the parties’ read of the statistical significance of the explanatory variables differs does not render Maestas’s opinions inadmissible.

The parties also dispute the significance of the R-squared statistical test. ECF No. 436 at 20–21; ECF No. 567 at 23–24. However, disputes about the weight of a statistical test are quintessentially jury questions and not questions of admissibility.

Maestas adequately explains that variation in quantity of Stelara demanded would not affect her conclusions because when accounted for, there is no change in the outcome variable—Stelara prescriptions. ECF No. 567 at 25 (“The equation is simple: no statistically significant variables + an unchanging constant = no statistically significant change in the dependent variable.”). And because failure to include a statistically insignificant variable in the regression does not render Maestas’s method opinion unreliable, it does not defeat admissibility, and J&J’s partial motion to exclude will be denied.

*ii. Anupam Jena*

Jena’s opinions are also admissible. Jena rebuts Maestas’s opinions on market power and opines that: (1) based on his analysis of clinical and economic substitutability, Stelara competes in markets broader than Stelara and Ustekinumab alone; (2) “Maestas’[s] analysis of direct evidence of market power is flawed because she misinterprets the economic significance of the evidence regarding Stelara’s pricing and margins;” and (3) Maestas’s assessment of J&J’s market power is “based on fundamentally flawed analyses of Stelara’s net prices and sales, unsound assessment of economic substitutability, and inappropriate application of the hypothetical monopolist test.” ECF No. 470-4 ¶¶ 16–29.

CareFirst challenges the relevance of Jena’s opinions, primarily arguing that he does not assess cross-price elasticity of demand and that his clinical

substitutability and ‘switching’ analyses should be excluded.<sup>5</sup> See ECF No. 476 at 19, 21–22. But “[w]hile the court agrees that [cross-price elasticity of demand] is the determinative legal question for . . . summary judgment on the relevant market, as discussed below, it is not the correct standard for excluding Jena’s opinions entirely.” *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 2:18-md-2836, 2021 WL 6689718, at \*10 (E.D. Va. Nov. 1, 2021), *report and recommendation adopted*, 587 F. Supp. 3d 356 (E.D. Va. 2022). Jena’s opinions on clinical and economic substitutability help the trier of fact assess the relevant market here even if he does not provide direct economic evidence of cross-price elasticity of demand. See *id.* (evaluating “evidentiary proxies . . . for cross-elasticity” such as “therapeutic alternatives, formulary placement, and own-price elasticity of demand” is “potentially helpful to the trier of fact” in evaluating market power); see also *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 2:13-md-2445, 2023 WL 5617784, at \*5 (E.D. Pa. Aug. 30, 2023) (“Functional interchangeability is one aspect of determining a relevant market.”).

CareFirst’s arguments about reliability similarly fail to show that Jena’s opinions are inadmissible. First, CareFirst contends that Jena “fails to consider the

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<sup>5</sup> CareFirst’s argument that the data Jena use for his switching analysis is flawed is really an argument about how Jena is reading the data, which goes to the weight of his opinions, not their admissibility. ECF No. 476 at 21–22. Even if Jena does not affirmatively state that the reason individual patients switched from Stelara to another drug was due to price, clinical switching data are still useful as evidence of potential “reasonable interchangeability.” See *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 2:13-md-2445, 2023 WL 5617784, at \*5 (E.D. Pa. Aug. 30, 2023) (considering “multiple real[-]world examples of switching among the products”).

scope of the challenged conduct in this case” and “refuses to consider the effect of biosimilar entry.” ECF No. 476 at 16–17. But Jena does consider the effect of biosimilar entry. *See* ECF No. 470-4 ¶¶ 22, 155–162, 168–70 (discussing why biologic manufacturers’ pricing does not represent the competitive price for Stelara). CareFirst’s grievance is with the relative weight Jena assigns to the price levels of biosimilar entry, which is not a proper basis for exclusion.

Second, CareFirst contends that Jena commits the Cellophane Fallacy whereby a firm already exercising monopoly power will experience switching when it increases its prices. ECF No. 476 at 23–24; *see Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 471 (1992) (“[T]he existence of significant substitution in the event of *further* price increases or even at the *current* price does not tell us whether the defendant *already* exercises significant market power.”). However, this argument again goes to the weight of Jena’s opinions, not their admissibility. Jena *does* examine whether J&J was pricing at supracompetitive levels and concludes that it was not, basing his opinion on evidence that J&J was benchmarking its prices and rebating practices against other drugs as well as non-price evidence such as marketing practices. ECF No. 476 at 25; ECF No. 470-4 ¶¶ 118–145.<sup>6</sup>

Third, CareFirst disputes Jena’s assessment of the alleged differences between biologic and biosimilar manufactures’ business models as an indicator of price

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<sup>6</sup> CareFirst also argues that Jena’s analyses of formulary placement and rebates as well as promotional expenditures are not relevant because they “are not evidence of substantial cross-elasticity.” ECF No. 476 at 25–26. But that is not reason to exclude the opinions. Such analyses *are* relevant to the question of cross-elasticity, even though they are not dispositive. *See In re Solodyn (Minocycline Hydrochloride)*

difference. ECF No. 476 at 27–30, 32. However, Jena adequately explains that he accounts for sunk costs like research and development because such costs are likely to affect biologic manufacturers’ pricing in the “long-run average cost.” ECF No. 470-6 ¶¶ 172–73. Therefore, such an assessment does not render Jena’s opinions inadmissible and so CareFirst’s motion to exclude will be denied.

***iii. Product Market Definition***

CareFirst alleges that the relevant product market is Stelara and biosimilar Ustekinumab. ECF No. 474 at 11. J&J, on the other hand, argues that “numerous other monoclonal antibodies approved to treat the same conditions as Stelara” compete in the same product market. ECF No. 576 at 11. CareFirst is not entitled to summary judgment on monopoly power because J&J raises a genuine dispute as to the relevant product market definition.

Measuring market power in the pharmaceutical industry begins with identifying therapeutic alternatives for the drug at issue and showing the economic interchangeability of those alternatives. *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 2:13-md-2445, 2023 WL 5617784, at \*6–7 (E.D. Pa. Aug. 30, 2023). The key consideration for economic interchangeability

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*Antitrust Litig.*, No. 1:14-md-2503, 2018 WL 563144, at \*9 (D. Mass. Jan. 25, 2018) (“That [the expert] uses a different economic analysis, one that explicitly considers the changes in effective pricing (*i.e.*, accounting for coupons, discounts and rebates) does not mean that such analysis fails to bear upon a showing of cross-elasticity of demand.”); *Meijer, Inc. v. Barr Pharms. Inc.*, 572 F. Supp. 2d 38, 55 (D.D.C. 2008) (explaining that marketing and promotional activities are relevant but not dispositive to the question of market power); *In re Zetia*, 2021 WL 6689718, at \*10 (admitting Jena’s market power opinions over a relevance objection based on “pricing, rebating, and other factors”).

is cross-price elasticity of demand. *Id.*; see also *It's My Party, Inc. v. Live Nation, Inc.*, 811 F.3d 676, 683 (4th Cir. 2016) (relevant market defined by cross-price elasticity of demand). But in the context of the pharmaceutical industry, “market power looks different from one case to the next,” and courts often examine the practical realities. *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 302 (D.R.I. 2019). Therefore, the Court will first examine cross-elasticity of demand and then secondarily consider practical realities of the industry.<sup>7</sup>

CareFirst measures cross-price elasticity of demand using natural experiments and the “Hypothetical Monopolist Test” (HMT) from the Department of Justice’s and the Federal Trade Commission’s *Horizontal Merger Guidelines*. ECF No. 474 at 16 ¶ 13. CareFirst also relies extensively on direct evidence of market power—evidence of increased prices, for example. *E.g.*, ECF No. 474 at 15–17 (discussing J&J’s price increases between 2010 and 2024); ECF No. 629 at 7 (discussing Stelara net prices after biosimilar entry). But because CareFirst expressly disclaimed reliance on direct evidence in its motion for summary

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<sup>7</sup> While J&J seeks to expand the economic consideration beyond cross-price elasticity of demand, ECF No. 576 at 12–13, as the Court in *In re Zetia* held, “therapeutic substitutability cannot replace the showing of cross-price elasticity key to defining the relevant product market.” 587 F. Supp. 3d 356, 364 (E.D. Va. 2022); see also *id.* at 361 (“[P]roducts which are interchangeable to some degree, but do not share significant cross-elasticity of demand, are not in the same relevant antitrust product market.”).

judgment,<sup>8</sup> the Court will not consider direct evidence in making its determination here.

As explained in Part III.A.i. above, Maestas’s regressions show “no evidence of economic substitution between Stelara and other products in the same therapeutic area.” ECF No. 488 ¶ 123. While her brand drug regression is not based on a price change, and instead shows clinical substitution, her biosimilar drug regressions *are* based on price change and therefore do demonstrate economic substitution. Maestas then conducted an HMT, which tests whether a hypothetical monopolist controlling Stelara and biosimilar Ustekinumab could profitably impose a small but significant and non-transitory increase in price. *Id.* ¶ 126. Maestas used “forecasted price erosion at the time [of] Stelara biosimilar entry” to conclude that the relevant market did not expand beyond biosimilar Ustekinumab because actual data [were] not yet available. *Id.* ¶ 127.

J&J disputes the relevance of the HMT in the pharmaceutical context because it “would render most brand name pharmaceutical companies [] *per se* monopolists prior to generic entry.” ECF No. 576 at 20 (quoting *Fed. Trade Comm’n v. AbbVie Inc.*, 329 F. Supp. 3d 98, 130 (E.D. Pa. 2018) (quotations marks and citation omitted), *rev’d on other grounds Fed. Trade Comm’n v. AbbVie Inc.*, 976 F.3d 327 (3d Cir. 2020)).

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<sup>8</sup> CareFirst seeks summary judgment on indirect evidence of market power only though it “reserve[s] the right to seek a directed verdict on market power based on the undisputed direct evidence.” ECF No. 474 at 11.

While J&J is correct that HMT alone could not demonstrate cross-price elasticity here, the Court need not disregard the test altogether.

However, J&J raises material issues of fact that prevent a finding of summary judgment as to indirect evidence of market power. Given that Maestas's only regression model that is based on price change is the biosimilar regression, that is the only model the Court can consider for the cross-elasticity of demand inquiry. Most importantly, while Jena's critiques of Maestas's model do not render her testimony inadmissible, they raise factual questions as to whether her model adequately factors in inputs such as overall Stelara demand—*i.e.*, whether the regressions “suffer from omitted variable bias.” ECF No. 576 at 18.

CareFirst relies on *In re Zetia* extensively for the proposition that there is no material issue of fact as to the natural experiments here. But this case is unlike *In re Zetia* because the plaintiffs in that case based their natural experiments on actual data of biosimilar entry. 2021 WL 6689718, at \*15–16. Additionally, the *Zetia* plaintiffs' market power expert used an “Almost Ideal Demand System” (AIDS) model to estimate “how change in one product's price affects demand for other products.” *Id.* at \*4. Thus, the defendants' arguments challenging the use of aggregate data and inputs were “at the margins” of the analysis and, even if factored into the models, did not change the cross-price elasticity conclusion. *Id.* Here, Maestas does not use biosimilar Ustekinumab entry data (because it is not yet available) and does not use AIDS or an equivalent pricing model. *See also In re Solodyn*, 2018 WL 563144, at \*8 (using AIDS to demonstrate cross-price elasticity). Though Maestas is free to use any

economic model she likes, her showing of cross-price elasticity is not strong enough to withstand the factual issues J&J raises.<sup>9</sup>

While J&J's rebating arguments standing alone may not have created a material issue of fact, they do bolster the question of whether Maestas adequately modeled cross-price elasticity. J&J argues that while J&J increased rebate payments from 2016 to 2024, its net price decreased 34.5% during that time. ECF No. 576 at 21. CareFirst argues that increased rebates were an industry trend but does not explain why J&J's net prices decreased. ECF No. 629 at 8. The fact that J&J sold more units and its net sales increased also does not explain why its *net price* decreased. *Id.* at 9. Net price is what J&J's customers paid and is thus the relevant inquiry. *Id.* at 16.

Overall, because J&J raises material questions regarding circumstantial evidence of market power, CareFirst's motion for summary judgment on monopoly power must be denied.<sup>10</sup>

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<sup>9</sup> CareFirst spends much of its briefing rebutting Jena's rebuttal report, but it does not explain why Maestas demonstrates cross-price elasticity.

<sup>10</sup> CareFirst asks the Court to strike a declaration from Jena that was based on "data and opinions available at the time his rebuttal report was due" and because it exceeds the Local Rules page limits for briefing. ECF No. 629 at 7 n.2. But CareFirst does not contend that this disputed declaration contains any new analysis. *See Abu-Eid v. Discover Prods., Inc.*, 589 F. Supp. 3d 555, 561 (E.D. Va. 2022) (denying motion to strike declaration because "the facts on which [an expert] relied in preparing for his declaration were disclosed to the plaintiff during discovery"); *Baltimore Aircoil Co., Inc. v. SPX Cooling Techs. Inc.*, No. 13-cv-2053, 2016 WL 4426681, at \*21–22 (D. Md. Aug. 22, 2016), *aff'd*, 721 F. App'x 983 (Fed. Cir. 2018) (denying motion to strike declarations because party had notice of the underlying opinions) (unpublished). The mere fact that Jena's declaration is based on data or opinions available at the time his rebuttal report was due does not render it inadmissible. Furthermore, CareFirst

## B. Fraud on the PTO

J&J seeks summary judgment on CareFirst's *Walker Process* fraud claim. *Walker Process* fraud requires "(1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the patent examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070–71 (Fed. Cir. 1998). A plaintiff must establish these facts by clear and convincing evidence. *Network Signatures, Inc. v. State Farm Mut. Auto. Ins. Co.*, 731 F.3d 1239, 1242 (Fed. Cir. 2013).

Because J&J is the party moving for summary judgment on this issue, the Court views the facts and inferences in the light most favorable to CareFirst. CareFirst argues that J&J withheld documents from the PTO examiner and made three misrepresentations during prosecution. CareFirst raises a genuine dispute as to whether J&J committed *Walker Process* fraud by omitting the Jostins, Granlund, and Ochsenkühn studies and by stating before the PTO that "[p]rior to the present invention, no studies had been conducted with [U]stekinumab for UC." But CareFirst

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does not provide any argument as to why Jena's declaration should be included in the briefing page limits—and the Court declines to do so. *Michael v. Sentara Health Sys.*, 939 F. Supp. 1220, 1225 n.3 (E.D. Va. 1996) ("[T]he application of the local rules is within the discretion of the Court.").

fails to raise a genuine dispute as to any other alleged omissions or misrepresentations.

*i. Materiality*

*a. Misrepresentations*

CareFirst alleges the following statements made to the PTO by J&J’s attorney were misrepresentations: (1) “it would not have been obvious that the endpoints [of NCT 236] would have been met by the claimed antibody [Ustekinumab]”; (2) “[p]rior to the present invention, no studies had been conducted with [U]stekinumab for UC;” (3) “[d]ue to the uncertainty of clinical outcomes and the failure of numerous medicines to satisfy designated clinical trial endpoints, the posting of elements of a clinical trial in advance of conduct of the trial do not anticipate or render obvious the subject matter of the claims.” ECF No. 566 at 20–21 ¶¶ 75, 78. In short, CareFirst argues that J&J falsely represented “that there was no reasonable expectation that NCT 236 would succeed,” *id.* ¶ 79, while J&J repeatedly represented to the FDA that “the science supported the reasonable assumption that [U]stekinumab w[ould] also be effective in UC,” based on the similarities to Crohn’s disease, *id.* at 25. CareFirst summarily states that “J&J[’s] statements to the PTO in October 2020 . . . were

material” and the “omissions speak for themselves” but does not make *any* showing of materiality. *Id.* at 24–25.

The Court initially dismissed CareFirst’s *Walker Process* claims based on misrepresentations<sup>11</sup> because the first amended complaint alleged that the patent examiner had NCT 236 before him, which allowed the patent examiner to reach his own conclusions about whether NCT 236 rendered the ’307 patent obvious. ECF No. 119 at 22–23. However, the Court allowed CareFirst to amend its complaint to correct its misunderstanding that the patent examiner had NCT 236 before him; instead, the patent examiner had a CT.gov web posting that disclosed NCT 236. ECF No. 592 at 6–12; ECF No. 641 ¶ 170 (“The examiner correctly rejected the ’509 application’s claims as either anticipated by or obvious over the CT posting, the second reference cited in his rejection. . . . his reference to and notes on the CT posting suggest that he saw a webpage titled “Study Details,” which provides the details of NCT 236.”). J&J did not oppose this amendment. ECF No. 592 at 6–12.

The new undisputed evidence shows that the patent examiner “listed the full CT.[g]ov website on a Notices of References cited,” including an access date. ECF No. 492 at 18 ¶ 28 (citing 457-1 at 179). The website included details about the protocol and status of the NCT 236 protocol, including outcome measures. *Id.*; ECF No. 474 at 39 ¶ 60. Additionally, after the patent examiner initially issued a non-final rejection

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<sup>11</sup> Specifically, the following purported misrepresentations: (1) “it would not have been obvious . . . [U]stekinumab would successfully treat ulcerative colitis;” and (2) NCT 236 “did not disclose or suggest that treating [ulcerative colitis] with [U]stekinumab would achieve a response as measured by any one of the seven known endpoints measures for ulcerative colitis treatment.” ECF No. 119 at 21–22.

of the '509 application, J&J amended the claims to include NCT 236's specific clinical endpoints. ECF No. 492 at 15 ¶ 21. CareFirst does not dispute these facts but only notes that "the record does not show the PTO having or considering . . . the NCT 236 protocol." ECF No. 566 at 19 ¶ 70; 27. But because the patent examiner had the fact of and details about NCT 236 before it, including the endpoints, it was "free to reach [its] own conclusion and accept or reject" J&J's claims that NCT 236 did not render the '307 patent obvious. *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007). The patent examiner need not affirmatively indicate that they reviewed the NCT 236 protocol. *See id.*; *see also Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008). Therefore, the first statement could not have been material to patentability.

The third statement is not objectively misleading, so CareFirst could not show that statement was a but-for cause of the patent's issuance. That clinical outcomes are uncertain or numerous medicines fail to satisfy designated clinical trial endpoints are both true statements that would not be misleading to a person of ordinary skill in the art. And in any event, CareFirst fails to address how this statement could affect the obviousness analysis. Simply asserting that J&J made this statement is not enough to present a genuine issue of fact as to materiality. *See Zoltek Corp. v. United States*, 95 Fed. Cl. 681, 694 (2010) (failure to explain *how* a factor would affect the obviousness analysis cannot defeat summary judgment).

The second statement, included in the '509 application, is the only statement that presents a genuine issue of material fact. Had the patent examiner known that

prior studies had been conducted with Ustekinumab for UC, then it is possible it would have rendered the patent obvious. Because the materiality of this statement is clear, summary judgment will be denied as to this statement alone. J&J argues that the face of the specification confirms that “studies” refers to “clinical studies” and it is “undisputed” that no clinical studies had been conducted for Stelara prior to UNIFI. ECF No. 492 at 34. But CareFirst disputes whether the Ochsenkühn study was clinical. *See* ECF No. 566 at 9 ¶¶ 5, 9. So even if “no studies” meant “no clinical studies,” CareFirst raises a genuine dispute as to whether the statement was material.

Therefore, CareFirst survives summary judgment as to the materiality of the statement, “[p]rior to the present invention, no studies had been conducted with [U]stekinumab for UC.”

*b. Omissions*

CareFirst challenges the omission of “(i) the NCT 236 protocol;<sup>12</sup> (ii) any of J&J’s submissions to the FDA or foreign health authorities regarding NCT 236; (iii) the Induction or Maintenance CSRs; and (iv) Jostins, Granlund, or Ochsenkühn.”<sup>13</sup> ECF No. 566 at 19 ¶ 69. But CareFirst only opposes summary judgment as to the

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<sup>12</sup> J&J refers to the NCT 236 protocol as the “UNIFI Protocol.” ECF No. 492 at 10 ¶ 5, 11 ¶ 8.

<sup>13</sup> J&J characterizes CareFirst’s *Walker Process* claim as based on three categories of omissions: (1) J&J’s postings to the CT.gov website; (2) J&J’s UNIFI-related submissions to the FDA; and (3) several prior art articles. ECF No. 492 at 26–27.

Jostins, Granlund, and Ochsenkühn studies, the NCT 236 protocol, and the Induction CSR.<sup>14</sup>

**Ochsenkühn Study** — CareFirst’s only *substantive* argument about materiality is in regard to the Ochsenkühn study:<sup>15</sup> It argues that the study “discloses the successful treatment of UC with the exact dose of [U]stekinumab as the ’307 patent claims” and that it “states its expectation that ‘large ongoing trials will confirm [its] findings and [U]stekinumab could become a new therapeutic option for refractory UC.” ECF No. 566 at 27. In further support of this argument, CareFirst notes that the PTO examiner “rejected the claims of a nearly identical application—the ’310 application—as obvious in light of” the study. *Id.* at 28.

In response, J&J argues that “Ochsenkühn’s abstracts are not but-for material because, as [] Ochsenkühn himself admitted, these abstracts do not disclose the claimed clinical endpoints of the ’307 [p]atent.” ECF No. 633 at 20 (emphasis omitted). But while Ochsenkühn’s deposition testimony does reveal that his study did not disclose all the claimed clinical endpoints of the ’307 patent, CareFirst contends that the study tested “the same dosing regimen claimed in the ’307 patent.” ECF No.

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<sup>14</sup> At no point does CareFirst define what it means by “any of J&J’s submissions to the FDA or foreign health authorities regarding NCT 236” (other than the protocol) and the “Maintenance CSRs,” ECF No. 566 at 19 ¶ 69, or what material information these documents might contain. CareFirst therefore has failed to create a genuine dispute of material fact as to these documents.

<sup>15</sup> CareFirst argues that the information J&J allegedly withheld from the PTO revealed that “J&J had a substantial scientific and clinical reason to expect that [U]stekinumab would effectively treat UC” that “justified skipping phase 2 efficacy trials entirely.” ECF No. 566 at 26. CareFirst then simply states that the omitted materials were not cumulative of information before the PTO. *Id.* at 26–27.

566 at 27. That the study tested the same dosing regimen and rendered the '310 application obvious establishes materiality sufficient to survive summary judgment.

**NCT 236 Protocol and Induction CSR** — CareFirst argues that while copying language into the '501 application (which became the background section for the '509 application), J&J patent manager Dr. Luis Ralat deleted language and studies from the NCT 236 protocol and the Induction CSR “regarding the similarities between Crohn’s and UC” and “J&J’s representations that those similarities provided a reasonable expectation that [U]stekinumab would effectively treat UC.” ECF No. 566 at 18–19 ¶¶ 67–68. CareFirst also states that J&J submitted NCT 236’s protocol to the FDA but not to the PTO. *Id.* at 16 ¶ 62, 19 ¶ 69. As explained above, however, the material details about the NCT 236 protocol were available to the patent examiner through the CT.gov posting.

CareFirst alleges three statements and citations to two studies were omitted:

- (1) “However, based on the similarities in the genetics and biology of UC and Crohn’s disease, it was reasonable to propose that [U]stekinumab may also be effective in the treatment of UC.” ECF No. 536-27 at 4.
- (2) “Th1- and Th17-related genes are upregulated considerably in the mucosa of both UC and Crohn’s disease patients, suggesting that once established, the inflammatory mechanisms at the mucosal level between the two diseases are largely the same; similar conclusions were reached in a genome-wide association study of IBD patients conducted by Jostins and colleagues.” ECF No. 536-27 at 8.
- (3) “These data, along with the shared biology of, and similar response to current treatments between, Crohn’s disease and UC provide a substantial

scientific and clinical rationale to justify a direct-to-Phase-3 approach to the study of [U]stekinumab in UC.” ECF No. 536-27 at 9.

- (4) Citations to Granlund and Jostins. ECF No. 536-27 at 10.

J&J, however, argues that this information was contained in the ’509 application and the ’307 patent specification, which were before the patent examiner. ECF No. 633 at 11. The ’509 application detailed that “biologic therapies that are currently approved for the treatment of UC have also demonstrated efficacy in Crohn’s disease.” ECF No. 492 at 14 ¶ 17; ECF No. 457-1 at 6 ¶ 10. The application also discusses that UC and Crohn’s disease are “mediated by Th1 or TH17 cells . . .” and the genetic relationship between the two. ECF No. 457-1 at 6 ¶ 10. Additionally, the ’509 application referenced the “efficacy and safety of intravenous (IV) [U]stekinumab as induction therapy in Crohn’s disease have been evaluated in clinical studies” where “[U]stekinumab demonstrated clinically significant efficacy compared with placebo.” ECF No. 457-1 at 6 ¶ 25, 7 ¶ 5. Therefore, J&J demonstrates that all three statements CareFirst contends were omitted were before the examiner and so the omission of the NCT 236 Protocol and Induction CSR was not material.

**Jostins and Granlund Studies** — Finally, while J&J contends that it sent articles that “disclose[d] [Crohn’s disease] and UC’s genetic relationship, including “one summarizing Jostins” to the PTO, it is unclear from the record which article disclosed the Jostins study and to what extent. ECF No. 633 at 12. J&J also never says that it disclosed the Granlund study. *See id.* CareFirst contends that the Jostins study stated, “nearly all the biological mechanisms involved in [Crohn’s] play some

role in [UC] and vice versa” and that both studies provided enough assurance to J&J of the probability of success of NCT 236 that it concluded a phase 2 study was unnecessary. ECF No. 566 at 13, ¶ 51, 16 ¶ 60. That is enough to create a material dispute of fact as to whether the omission of those studies was material.

Therefore, CareFirst raises a genuine dispute as to the Jostins, Granlund, and Ochsenkühn omissions only.

***ii. Intent to Deceive***

“Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). But to establish intent based on circumstantial evidence, “intent to deceive the PTO must be ‘the single most reasonable inference able to be drawn from the evidence.’” *In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 519 (Fed. Cir. 2012) (quoting *Therasense*, 649 F.3d at 1291). Where “multiple reasonable inferences” as to intent “may be drawn, intent to deceive cannot be found.” *Therasense*, 649 F.3d at 1290–91. “A court can no longer infer intent to deceive from non-disclosure of a reference solely because that reference was known and material.” *1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1372–73 (Fed. Cir. 2012).

CareFirst attempts to lower this standard by citing *Unigene Lab’ys Inc. v. Apotex, Inc.*, 655 F. 3d 1352, 1358–59 (Fed. Cir. 2011), a case which cites an earlier recitation of the *Walker Process* fraud elements but does not discuss the intent requirement in any meaningful way. *Id.* at 1359; ECF No. 566 at 28–29. Indeed,

numerous cases since *Apotex* have confirmed that the standard articulated in *Therasense* is the prevailing standard. *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1291–92 (Fed. Cir. 2012); *Ohio Willow Wood Co. v. Alps S., LLC*, 813 F.3d 1350, 1357 (Fed. Cir. 2016); *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1353 (Fed. Cir. 2021).

*a. Jostins and Granlund Studies*

CareFirst argues J&J intended to deceive the PTO by omitting the Jostins and Granlund studies because: (1) Ralat deleted references to Jostins and Granlund because J&J’s goal in front of the PTO was patent issuance; (2) Ralat reported to Dichter and so he knew of Ralat’s deletion; (3) Dichter was on the team that designed NCT 236 and knew the company very well; (4) J&J’s counsel “shielded from discovery conversations between him and the inventors about the protocol and FDA submissions”;<sup>16</sup> and (5) the inventors “marshalled scientific evidence to support” the expectation that Ustekinumab would successfully treat UC, including Jostins and Granlund. ECF No. 566 at 31–34.

CareFirst relies on the following pieces of evidence in support of its argument: (1) citations in J&J’s FDA submission for the proposition that duty-bound J&J employees knew about the Jostins and Granlund studies, *see, e.g.*, ECF No. 563-1 at

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<sup>16</sup> This argument will not be considered. A trier of fact cannot draw an adverse inference “from invocation of the attorney-client . . . privilege.” *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344 (Fed. Cir. 2004) (“Although this court has never suggested that opinions of counsel concerning patents are not privileged, the inference that withheld opinions are adverse to the client’s actions can distort the attorney-client relationship, in derogation of the foundations of that relationship.”).

65; ECF No. 563-6 at 16; ECF No. 534-1 at 30; and (2) Ralat's deletion of the description of and citations to Jostins and Granlund.

J&J contends that "while certain '307 [p]atent inventors reviewed documents that *cited* the Jostins/Granlund articles, there is no evidence that they read or reviewed the Jostins/Granlund articles themselves." ECF No. 492 at 31–32. J&J is correct. CareFirst cannot meet its burden of demonstrating intent by pointing to citations in very lengthy briefing documents submitted to the FDA. *See In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d at 519 ("[I]ntent to deceive the PTO must be the single most reasonable inference able to be drawn from the evidence.") (quotations and citations omitted).

However, CareFirst can survive summary judgment on intent as to Ralat. J&J argues that Ralat's conduct is irrelevant to the *Walker Process* claim because he was only involved in preparing the patent application and not the patent. But *Walker Process* fraud is actionable against those "associated with the filing and prosecution of a patent application" who owe "a duty of candor and good faith" to the PTO. 37 C.F.R. § 1.56(a), (c). That includes "[e]ach attorney or agent who prepares or prosecutes the application" and "[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to

assign the application.” *Avid Identification Sys., Inc. v. Crystal Imp. Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010); 37 C.F.R. § 1.56(c). Here, that list includes Ralat.

CareFirst shows that Ralat deleted references to Jostins and Granlund, which is enough to support the conclusion that a jury could reasonably infer that Ralat “had the requisite intent to defraud the PTO based on his failure to disclose the reference[s] to the PTO.” *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1072 (Fed. Cir. 1998) (intent supported by deletion of references to prior art). A jury could also reasonably conclude that intent to defraud was “the single most reasonable inference.” *In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d at 519.

*b. Ochsenkühn Study*

CareFirst argues that several inventors had “Ochsenkühn in their files, often from multiple sources” and attended conferences where Ochsenkühn presented his research. ECF No. 566 at 34–35. And while CareFirst acknowledges that the inventors claim a lack of recollection, it argues that the question of whether the inventors knew about this study is a jury question. *Id.* at 35. Bolstering their argument, CareFirst points to the fact that “J&J sponsored [] Ochsenkühn to present the same research at a U.S. conference, including at a special session on his research for J&J, a few months after he had presented it at a European conference attended by a ’307 inventor.” *Id.* (emphasis removed).

J&J argues that “while certain ’307 [p]atent inventors . . . received emails summarizing or attaching [] Ochsenkühn’s abstracts along with numerous other abstracts or reports, these employees did not even know that they had these abstracts

in their files, let alone read them.” ECF No. 492 at 31. J&J also contends that no duty-bound J&J employee met Ochsenkühn at his conference or attended his special session. *Id.* at 31 n.12.

But CareFirst creates a genuine dispute as to whether a reasonable jury could conclude that J&J’s failure to disclose the Ochsenkühn study was intentional. A reasonable jury could conclude from the evidence that at least one duty-bound employee knew about the very study that J&J invited Ochsenkühn to present on, knew about its materiality, and decided to withhold it from the patent application and prosecution. *Cf. In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 313 (D.R.I. 2019) (a jury could infer knowledge where “other pertinent executives” knew about the study).

*c. Misrepresentation*

J&J argues that CareFirst cannot demonstrate that J&J believed that the statement “[p]rior to the present invention, no studies had been conducted with [U]stekinumab for UC,” included in the ’509 patent application, was inaccurate. ECF No. 633 at 18. As explained above, a reasonable jury could infer that Ralat had knowledge of the falsity of the statement based on his deletion of the Jostins and Granlund studies. A reasonable jury could also conclude that Ralat’s intent in drafting that statement was to deceive the FDA because he explained his deletions

were based on the different “goal[s]” of an FDA submission versus a PTO submission. ECF No. 566 at 18–19 ¶ 68.

Therefore, J&J’s motion for summary judgment as to the *Walker Process* fraud claim is denied as to the Jostins, Granlund, and Ochsenkühn studies and the statement, “[p]rior to the present invention, no studies had been conducted with [U]stekinumab for UC” but granted as to all other purported omissions and misrepresentations.

### C. J&J’s Acquisition of Momenta Patents

CareFirst’s claim that J&J’s acquisition of four Momenta manufacturing patents<sup>17</sup> constitutes a “willful acquisition or maintenance of [monopoly] power—as opposed to simply superior products or historic accidents,” survives summary judgment. *E.I. du Pont de Nemours & Co.*, 637 F.3d at 441 (citing *Eastman Kodak Co. v. Image Tech Servs., Inc.*, 504 U.S. 451, 480 (1992)).

The analysis here turns on the definition of “willful” and what—if any—intent CareFirst must demonstrate J&J had to monopolize. The parties present starkly contrasting views of the caselaw: CareFirst attests that “[w]illfulness requires ‘mere intent to do the act.’” ECF No. 474 at 29 (citing *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd. (Actos)*, 11 F.4th 118, 137 (2d Cir. 2021)). J&J argues that a “willful acquisition” is one where “a defendant acted for anticompetitive purposes” and requires that “a jury

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<sup>17</sup> Momenta had “more than 500 patents” at the time of the acquisition. ECF No. 576 at 26.

could find no valid business reason or concern for efficiency’ for the conduct.” ECF No. 576 at 24–25 (quoting *Oksanen v. Page Mem’l Hosp.*, 945 F.2d 696, 710 (4th Cir. 1991)); ECF No. 492 at 39.<sup>18</sup> The Fourth Circuit’s most recent, and thus controlling, articulation of the willfulness standard is whether the defendant “intended to ‘exclude rivals on some basis other than efficiency.’”<sup>19</sup> *2311 Racing LLC v. Nat’l Ass’n*

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<sup>18</sup> Under *Oksanen* and its predecessor, *White v. Rockingham Radiologists, Ltd.*, the standard is whether a reasonable jury could find no valid business reason for the acquisition of Momenta. See *Oksanen*, 945 F.2d at 710; *White v. Rockingham Radiologists, Ltd.*, 820 F.2d 98, 105 (4th Cir. 1987). The Fourth Circuit has never overruled *White*, and some cases in this Circuit continue to rely on the ‘no valid business reason’ standard. But this Court follows the Fourth Circuit’s most recent articulation of the willfulness standard. In any event, the *White* court misstated the Supreme Court standard at the time by erroneously quoting language which was merely discussing the lower court’s jury instruction. *White*, 820 F.2d at 105 (quoting *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 597 (1985)). The *Aspen Skiing* Court explained that because “the jury was unambiguously instructed that Ski Co.’s refusal to deal with Highlands ‘does not violate [§] 2 if valid business reasons exist for that refusal,’ [the Court] must assume that the jury concluded that there were no valid business reasons for the refusal.” *Id.* at 604–05. The Court went on to rely on the assumption that there were no valid business reasons for the refusal to deal but did *not* say that a plaintiff must always prove the lack of a business justification in attempting to prove monopolization. See also *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 460 (7th Cir. 2020) (explaining that the Court in *Aspen Skiing* was “reviewing a jury verdict” and that “[v]alid business justifications are relevant only to the rebuttal of a *prima facie* case of monopolization”). Therefore, *White* incorrectly reads *Aspen Skiing*.

<sup>19</sup> The Fourth Circuit’s most recent articulation of the monopolization standard is also inconsistent with Supreme Court precedent. Under the Supreme Court’s scheme, there are two categories of potential Section 2 violations: Certain restraints are *per se* illegal because “the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output.” *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 19–20 (1979). And other restraints merit a “rule of reason” analysis because the effect on competition is less clear. *NCAA v. Bd. Of Regents of U. Okla.*, 468 U.S. 85, 103 (1984). The rule of reason inquiry is a “three-step, burden-shifting framework.” *Ohio v. Am. Express Co.*, 585 U.S. 529, 541 (2018). First, “the plaintiff has the initial burden to prove that the challenged restraint has

*for Stock Car Auto Racing, LLC*, 139 F.4th 404, 410 (4th Cir. 2025) (quoting *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 (1985)); *Duke Energy Carolinas, LLC v. NTE Carolinas II, LLC*, 122 F.4th 120, 122 (4th Cir. 2024).

CareFirst incorrectly states that “[t]his Court laid out the four factors that would be sufficient, if proven, to establish the acquisition as a [§] 2 exclusionary practice: (1) ‘defendants are monopolists’; (2) ‘defendants acquired exclusive rights in four patents covering some of the processes used to make biosimilars’; (3) ‘defendants are not biosimilar producer’; and (4) ‘defendants asserted the acquired patents in subsequent litigation.’” ECF No. 474 at 21 (citing ECF No. 119 at 33). The Court held that those allegations were sufficient to plead monopolization *not* that those allegations would be sufficient to prove monopolization at a later stage. ECF No. 119 at 33 (“At this stage . . . the Court finds the following allegations sufficient . . .”). The parties did not raise intent at the motion to dismiss stage, so the Court did not

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a substantial anticompetitive effect that harms consumers in the relevant market.” *Id.* Second, “[i]f the plaintiff carries its burden, then the burden shifts to the defendant to show a procompetitive rationale for the restraint.” *Id.* Third, “[i]f the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means.” *Id.* at 542.

Under this framework, intent is not expressly contemplated and certainly not required. Areeda & Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 651 (2025) (“The critical point is that the nature and consequences of a particular practice are the vital consideration, not the purpose or intent.”). However, evidence of “knowledge of intent may be [] helpful in cases involving practices . . . which can have numerous explanations and are very difficult to characterize as competitive or anticompetitive.” *Id.* Therefore, where, as here, the conduct alleged is not commonly before courts, intent is helpful but not determinative as to whether J&J’s acquisition of the Momenta patents was anticompetitive.

address it. *See* ECF No. 46 at 21–22 (memorandum in support of motion to dismiss); ECF No. 57 at 14–18 (opposition); ECF No. 65 at 9–13 (reply).

In any event, applying the Fourth Circuit’s current monopolization standard, CareFirst has raised a genuine dispute of material fact as to whether J&J “intended to exclude rivals on some basis other than efficiency.”

First, the parties dispute whether the relevant inquiry focuses on the acquisition at the time it was made or factors future conduct into the analysis. But the law is clear that the inquiry is whether “at the time of the patent acquisition” it was “reasonably foreseeable” that the acquisition would permit the acquirer to “obtain monopoly power in a relevant product market.” *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1208–09 (2d Cir. 1981); *see also id.* at 1205 (“Surely, a § 2 violation will have occurred where, for example, the dominant competitor in a market acquires a patent covering a substantial share of the same market *that he knows when added to his existing share* will afford him monopoly power.”) (emphasis added). Thus, “the focus should be upon the market power that will be conferred by the patent in relation to the market position then occupied by the acquiring party.” *Id.* at 1208.

Second, the parties contest whether the intent inquiry focuses on the Momenta manufacturing patents specifically, or on the Momenta acquisition in its entirety. In the absence of any case law analyzing a situation in which a potential monopolist acquired a company and its entire patent portfolio, only a fraction of which had the potential to be anticompetitive, this Court looks to how courts generally analyze company acquisitions. The inquiry there is whether “the acquired assets . . . were

either actual competitors or else reasonably constituted nascent threats to [the acquirer's] monopoly at the time of their acquisitions.” Areeda & Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 701 (2025) (quotations omitted). In other words, courts look to the business as a whole. Therefore, the focus should be on the acquisition in its entirety, and the relevant question is whether J&J could have reasonably considered Momenta, through its manufacturing patents, to be a potential competitor and therefore a “nascent threat” to J&J’s alleged monopoly power.

Such a focus requires knowledge on the part of J&J of Momenta’s manufacturing patents. J&J argues that at the time of the acquisition, it was not aware of the manufacturing patents nor was it aware that any biosimilar applicant might have used the patented cell culture media in the future. ECF No. 492 at 41. J&J says that it performed no diligence on the patents at issue and did not assign value to “nor even mention[]” the patents in its valuation of the Momenta acquisition. *Id.* at 20 ¶ 35; *id.* at 40. Instead, J&J “pursued Momenta because it wanted to commercialize nipocalimab” and so “patent-related transaction diligence was limited to patents related to nipocalimab.” ECF No. 576 at 26–27; ECF No. 492 at 40.

CareFirst argues that J&J had knowledge of the manufacturing patents during its due diligence as early as July 2020. ECF No. 474 at 29; *id.* at 22 ¶ 17. It bases this primarily on J&J’s Global Head of IP Litigation Denise DeFranco’s purported knowledge. CareFirst contends that DeFranco “reviewed at least two Momenta [manufacturing] patents before J&J acquired Momenta” and that she

testified that internal emails “ma[d]e [her] believe that J&J’s pre-litigation diligence concerning one Momenta patent started as early as August 2020.” ECF No. 566 at 10–11 ¶¶ 33, 35.

A review of CareFirst’s cited evidence reveals the following: (1) the patents were listed in the draft and executed merger agreement, ECF No. 471-3 at 12:8–17:23, 18:5–20:8; *see generally* ECF No. 471-6; (2) a privilege log created during the course of the Momenta acquisition shows that DeFranco had one of the relevant patents (the ’168 patent) in her file in June 2020 as well as an email with the subject/file name listed as the patent number, ECF No. 561-6; ECF No. 629 at 23–24 ¶ 112; (3) metadata of produced PDFs reveal that DeFranco and Dichter had copies of the ’168 patent in their files, ECF No. 647-1 at 6; (4) DeFranco testified that after looking at several internal emails and “log entries,” she “believe[d] that [J&J’s] pre-[Amgen] lit[igation] diligence started as early” as August 2020, ECF No. 561-7 at 34:19–21; (5) DeFranco testified that “[i]n 2020, after the acquisition . . . I got a list of patents from Momenta and forwarded them to [the attorneys handling the merger]. I did not study them. I did not look at them. I became aware of the manufacturing patents after we got Amgen’s information, and the patents were called out to my attention,” *id.* at 28:3–29:17; (6) several emails between J&J’s attorneys in June 2020 referenced Stelara, ECF No. 647-1 at 8–9; (7) J&J has not divested, sold, nor

surrendered its interests in the patents, despite divesting another Momenta asset. ECF No. 474 at 23 ¶ 25.

These facts raise a genuine dispute as to whether DeFranco had knowledge beyond mere awareness of the patent number—that is, whether J&J had meaningful knowledge of the four Momenta patents in such a way that J&J could view Momenta as a potential competitor or nascent threat in any potential relevant market.<sup>20</sup> Therefore, neither party prevails on summary judgment.<sup>21</sup>

#### **D. Antitrust Injury**

Questions of fact prevent summary judgment on the question of antitrust injury as well. “Antitrust injury encompasses two concepts: (1) the causal connection

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<sup>20</sup> J&J additionally contends that “[f]or J&J to have had the requisite intent to monopolize a market by acquiring these patents, it would have needed to know . . . how the biosimilar manufacturers might manufacture their product.” ECF No. 576 at 27–28. This is not a persuasive argument. While J&J asserts there are several ways to make biologics without using the methodology at issue in its patents, it does not say anything about the probability of a biologic using the methodology at issue. Therefore, on the evidence presented, it would be reasonable for a jury to conclude that J&J would have known a biosimilar manufacturer was likely to use the method at issue in the patent.

<sup>21</sup> Even applying the *Am. Express* three-step burden-shifting framework, the Court would deny summary judgment. Briefly, there is a genuine factual dispute at the first step—as to whether the acquisition had anticompetitive effect. J&J argues that the Court must examine the anticompetitive effect at the time the acquisition took place in 2020. But as explained above, the inquiry is whether, at the time of the acquisition, J&J could have reasonably foreseen future anticompetitive effect. *See Areeda & Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 707e (2025) (“By acquiring a patent, the monopolist might prevent present or *future* competition challenging its monopoly.”) (emphasis added).

CareFirst puts forward evidence that absent the Momenta patent acquisition, biosimilars would have entered the U.S. market earlier, which would have lowered Ustekinumab prices earlier. ECF No. 566 at 42 ¶¶ 95–102. However, J&J puts

between the plaintiff's injury and an antitrust violation, and (2) whether the plaintiff's injury was of a type that Congress sought to redress in providing a private remedy for violations of the antitrust laws." *Steves & Sons, Inc. v. JELD-WEN, Inc.*, 988 F.3d 690, 710 (4th Cir. 2021) (internal citation and quotations omitted). CareFirst's purported injury is the payment of higher prices for Ustekinumab due to J&J's anticompetitive conduct delaying generic competition from Amgen and six other biosimilar manufacturers.

J&J (briefly) argues only that the causation requirement is not met here—that the biosimilar entry dates are the result of the biosimilar manufacturers' "rational, independent business decisions to enter into settlement agreements with J&J, not from J&J's conduct." ECF No. 492 at 43. J&J relies on the following facts in support of its argument: (1) J&J sued Amgen for infringement of the '307 patent on November 29, 2022; (2) after receiving confidential documents from Amgen during litigation, J&J asserted the Momenta patents when moving for a preliminary injunction on March 1, 2023; (3) Amgen had "every incentive to launch its biosimilar Stelara as

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forward evidence that raises a genuine dispute about whether at the time of the Momenta acquisition it could have reasonably foreseen this anticompetitive effect: (1) J&J's pre-acquisition due diligence focused on nipocalimab, which was the "value driver" of the Momenta acquisition, ECF No. 494-10 at 39:5–24, 42:1–43:10; ECF No. 494-13 at 5; *see generally* ECF No. 494-11; (2) J&J's patent-related diligence was limited to patents that may impact nipocalimab and did not include the four manufacturing patents, ECF No. 494-14 at 5:24–6:25, 7:5–23, 8:16–20, 12:10–15, 17:10–18, 20:25–21:24 (J&J's 30(b)(6) witness confirming "there was no diligence on the four manufactured [] patents that [J&J] purchased from Momenta concerning the manufactur[ing] of biosimilar products); and (3) at the time of the Momenta acquisition, J&J was not aware of what cell culture media any potential biosimilar applicant for Ustekinumab might use, ECF No. 494-18 at 6:7–7:4, 10:14–11:18, 15:17–16:19, 17:19–18:8; ECF No. 494-16 ¶¶ 84, 94–100.

early as possible, yet chose to settle with J&J,” giving it a royalty-free non-exclusive license to enter as of January 1, 2025; (4) other biosimilar applicants had an incentive to launch as early as possible but also chose to settle; (5) CareFirst’s experts confirmed that a “reasonable biosimilar manufacturer would launch its biosimilar [U]stekinumab . . . as soon as possible and despite J&J’s ’307 patent.” ECF No. 492 at 21–22 ¶¶ 40–45.

In response, CareFirst argues that absent J&J’s use of the ’307 and Momenta patents, Amgen and subsequent biosimilar Ustekinumab competitors would have entered the market a year earlier. ECF No. 566 at 44–46. CareFirst does not challenge the settlements as unlawful, but rather attacks the “anticompetitive scheme” that led to the settlements. *Id.* at 45–46.

The settlements at issue here are not immune from antitrust scrutiny. *See FTC v. Actavis*, 570 U.S. 136, 158 (2013) (a settlement “can bring with it the risk of significant anticompetitive effects” which may “outweigh the single strong consideration—the desirability of settlements”); *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 161–63 (3d Cir. 2017), *sub nom.*, No. 15-2875, 2017 WL 3529114 (3d Cir. Aug. 9, 2017) (settlement in patent context not immune from antitrust scrutiny). However, CareFirst challenges events earlier in the causal chain—J&J’s alleged anticompetitive acquisition of the Momenta patents and the ’307 patent. *See In re Zetia*, 2022 WL 4355149, at \*24 (litigation holding that a patent

was valid and enforceable does not negate antitrust harm caused by earlier anticompetitive conduct—*i.e.*, conduct earlier in the causal chain).

As explained above in Parts III.B. and III.C., there are factual questions about whether the alleged anticompetitive conduct violates Section 2. But making all inferences in CareFirst’s favor, as is required at this stage, a reasonable jury could find that J&J’s anticompetitive conduct caused CareFirst’s antitrust injury. That is, but for J&J’s anticompetitive acquisition of the Momenta patents and the ’307 patent, the biosimilars would not have settled with J&J and would not have delayed market entry. *See Bio-Rad Laboratories, Inc. v. 10X Genomics, Inc.*, 483 F. Supp. 3d 38, 55 (D. Mass. 2020) (“litigation can constitute antitrust injury” even when protected by *Noerr-Pennington* if it constitutes a “separate Sherman Act violation”) (internal citations omitted); *cf. In re Androgel Antitrust Litig. (No. II)*, No. 1:09-CV-955-TWT, 2018 WL 2984873, at \*11 (N.D. Ga. June 14, 2018) (“Paying [generics] to stay out of the market for the purpose of avoiding the risk of competition is an antitrust harm, *regardless* of whether or not the patent is actually valid and infringed.”). Therefore, the Court must deny J&J’s motion for summary judgment as to antitrust injury.

#### IV. CONCLUSION

Plaintiffs CareFirst of Maryland, Inc., Group Hospitalization and Medical Services, Inc., and CareFirst Bluechoice, Inc.’s motion for partial summary judgment (ECF No. 442) is **DENIED**.

Defendants Johnson & Johnson and Janssen Biotech, Inc.'s motion for summary judgment (ECF No. 441) is **GRANTED IN PART** and **DENIED IN PART**, as described herein.

CareFirst's motion to exclude the expert opinions and testimony of Anupam Jena (ECF No. 450) and J&J's motion to exclude the expert opinions and testimony of Nicole Maestas (ECF No. 435) are **DENIED**.

**IT IS SO ORDERED.**



/s/

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Jamar K. Walker  
United States District Judge

Norfolk, Virginia  
December 15, 2025